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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,202	05/09/2001	Allan F. Platt	82012-1020	4797

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THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP
100 GALLERIA PARKWAY, NW
STE 1750
ATLANTA, GA 30339-5948

EXAMINER

GOTTSCALK, MARTIN A

ART UNIT PAPER NUMBER

3626

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,202

Applicant(s)

PLATT ET AL.

Examiner

Martin A. Gottschalk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 6 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/09/2001</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-24 have been examined.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5-6, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaston-Johansson (US Pat# 5,692,500, hereinafter Gaston-Johansson).

- A. As per claim 1, Gaston-Johansson discloses a method for quantifying a pain condition of a patient, the method comprising the steps of:

acquiring pain episode data for the patient (Gaston-Johansson: col 7, lns 48-54, note "...a multidimensional indication of the pain being experienced by a person can be obtained...");

performing pain assessment on the patient (Gaston-Johansson: col 7, ln 48 to col 8, ln 6); and

generating a multidimensional pain score that quantifies a pain condition for the patient (Gaston-Johansson: col 8, Ins 12-20; also see table labeled "EXAMPLE" and note the section labeled "Pain Intensity Scores").

B. As per claim 5, Gaston-Johansson discloses the method of claim 1, further comprising the step of:

generating an intervention required notice when the multidimensional pain score exceeds a predetermined intervention level (Gaston-Johansson: col 8, Ins 40-54; The Examiner considers the sensory score exceeding the emotional score to be a form of intervention required notice, indicating the indicated intervention to reduced the sensory component of pain.);

C. As per claim 6, Gaston-Johansson discloses the method of claim 1, further comprising the step of:

(a) generating a factor score for each of a plurality of pain factors (Gaston-Johansson: col 8, Ins 12-20; also see table labeled "EXAMPLE" and note the section labeled "Pain Intensity Scores". The Examiner considers the individual "Sensory" and "Emotional" descriptors, to be forms of pain factors. The same holds true when each of the individual categories "Sensory" and "Emotional" are taken in aggregate.); and

(b) generating an intervention required notice when the factor score exceeds a predetermined intervention level (rejected as per the reasons provided for claim 5

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above).

- D. As per claim 18, Gaston-Johansson discloses the system of claim 12, wherein the system is a hand-held device (Gaston-Johansson: col 1, 5-13).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaston-Johansson as applied to claim 1 above, and further in view of Kolb et al (Kolb, Bryan, and Whishaw, Ian Q. "Fundamentals of Human Neuropsychology." Third Edition; W. H. Freedman and Company, New York, 1990. Chapter 27, "Neuropsychological Assessment.").

A. As per claim 2, Gaston-Johansson fails to disclose the method of claim 1, wherein the step of the performing pain assessment further comprises the step of:

determining if the patient is cognitively impaired.

However, this feature is well known in the art as evidenced by the teachings of Kolb.

Kolb teaches the broad and well known application neuropsychological principals to the assessment of cognitive capacity (Kolb: pg 754, col 2, section labeled "Goals of Neuropsychological Assessment", paragraph 2.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the teachings of Kolb within the method of Gaston-Johansson with the motivation of facilitating patient care and rehabilitation, particularly if the pain experienced by the patient is associated with or residual to treatments of neurological conditions such as brain cancer (neoplasms) or (cerebro-) vascular abnormalities such as neurosurgery. Such assessment would help the patient and the patient's family to plan rehabilitation programs and realistic life goals (Kolb: pg 754-755, col 2, section labeled "Goals of Neuropsychological Assessment").

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B. As per claims 3, Gaston-Johansson discloses the method of claim 2, wherein the step of the performing pain assessment further comprises the step of:

acquiring a plurality of implicit pain factors if the patient is cognitively impaired, wherein the implicit pain factors are selected from the group consisting of

patient emotion (Gaston-Johansson: col 4, lns 50-67),

patient movement,

patient facial cues,

patient verbal cues,

patient position,

patient guarding areas,

observed therapy side effects and

observed therapy side effect level.

C. As per claim 4, Gaston-Johansson discloses the method of claim 2, wherein the step of the performing pain assessment further comprises the step of:

acquiring a plurality of explicit pain factors if the patient is not cognitively impaired,

wherein the explicit pain factors are selected from the group consisting of

pain intensity (Gaston-Johansson: col 3, lns 5-12, note "intensity"),

patient mood,

therapy side effects and

pain relief.

7. As per claims 7-11 (system), 12-17 (system) and 19-24 (computer readable medium) they are system computer readable claims which repeat the same limitations of claims 1 and 3-6, the corresponding method claims, as a collection of elements and logic steps as opposed to a series of process steps. Since the combined teachings of Gaston-Johansson and Kolb disclose the underlying process steps that constitute the methods of claims 1 and 3-6, it is respectfully submitted that they provide the underlying

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structural elements and logic that perform the steps as well. As such, the limitations of claims 12-17 and 19-24 are rejected for the same reasons given above for claims 1 and 3-6. The particular correspondence is as follows:

Claim 1 corresponds to claims 7, 12 and 19.

Claim 3 corresponds to claims 8, 13 and 20.

Claim 4 corresponds to claims 9, 14 and 21.

Claim 5 corresponds to claims 10, 17 and 24.

Claim 6a corresponds to claims 11a, 15 and 22.

Claim 6b corresponds to claims 11b, 16 and 23.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin A. Gottschalk whose telephone number is (571) 272-7030. The examiner can normally be reached on Mon - Fri 8:30 - 5.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MG
09/30/2005



JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER